J1403 - Pilot Study of a Surgery and Chemotherapy-Only Approach in the Upfront Therapy of Children with Wnt Positive Standard Risk Medulloblastoma

NCT02212574

May 11, 2016

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol Title: **Pilot Study of a Surgery and Chemotherapy-Only Approach in the Upfront Therapy of Children with Wnt Positive Standard Risk Medulloblastoma**

Application No.: **NA_00091840**

Sponsor: **Matthew Larson Foundation**

Principal Investigator: **Kenneth Cohen, MD, MBA**
Johns Hopkins Hospital
Bloomberg 11379
1800 Orleans St.
Baltimore, MD 21287
Phone 410-614-5055
Fax 410-955-0028

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.

- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.
- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.
- If children and adults can join this study, the word "you" in this consent form will refer to both you and your child.

2. Why is this research being done?

This research is being done to see if children with Wnt-positive medulloblastoma can be treated successfully without the use of radiation therapy.

Your brain tumor has been tested and shown to be Wnt-positive. Children with Wnt-positive medulloblastoma are almost always cured when given radiation therapy and chemotherapy after the removal of their tumor. However, radiation therapy to the brain and spinal cord results in a number of side effects including hair loss, irritation or redness of the skin, inflammation and irritation of the areas of the ear canal, and balance problems. Long-term side effects include increased risk of radiation induced high grade cancers, increased risk of inflammation to the blood vessels of the brain, with risk of stroke, growth failure, vision problems, partial hearing loss, memory loss, and learning difficulties.

Researchers are testing whether the total amount of treatment received after surgery can be safely reduced to try and decrease some of the side effects of treatment, and still maintain this excellent outcome. There are different ways this can be done including:

- Giving some radiation, but less than is usually given
- Giving some chemotherapy, but less than is usually given
- Giving no radiation

In this study, we will test the third option (giving no radiation). Children with Wnt-positive medulloblastoma may join.

How many people will be in this study?

Up to 13 children may join this study across participating centers. At Johns Hopkins, only one person is expected to enroll.

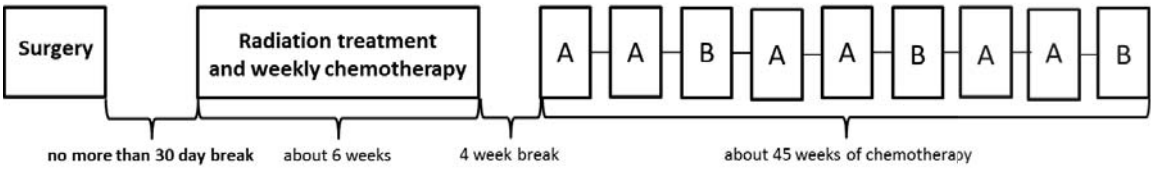
3. What will happen if you join this study?

If you agree to join this study, we will ask you to do the following things:

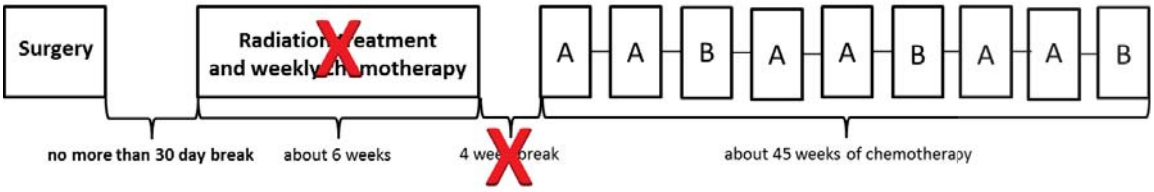
The only difference between the research therapy and the standard treatment for Wnt-positive medulloblastoma you will receive is that you will not receive radiation therapy or the weekly chemotherapy that is given during radiation treatment. All of the chemotherapy that is standardly given following radiation will occur, along with the normal monitoring during the chemotherapy treatment

This is shown in the following pictures:

Standard Therapy for Wnt-positive Medulloblastoma



Research Therapy for Wnt-positive Medulloblastoma without Radiation



Information about the standard chemotherapy and associated monitoring is included at the end of this consent form.

How long will you be in the study?

The chemotherapy treatment will last for about one year. After the completion of treatment, you will be followed for an additional 5 years.

4. What are the risks or discomforts of the study?

The major risk of this study is that by not giving the radiation treatment, your tumor will come back. If this happens, more treatment could be given including more surgery, radiation therapy and more chemotherapy. However, it is possible that despite given more treatment if the tumor comes back, your doctors will not be able to treat the tumor and you would die of your disease or a complication of this treatment.

Information about the risks of the standard chemotherapy are included at the end of this consent form. These risks would be the same whether you agree to participate in this study or not.

5. Are there risks related to pregnancy?

Women should not become pregnant and men should not father a baby while on this study because the drug(s) in this study can be bad for an embryo or fetus. If you or your partner can get pregnant, it is important for you to use birth control or not have sex while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some birth control methods might not be approved for use in this study.

Women should not breastfeed a baby while on this study. Also check with your doctor about how long you should not breastfeed after you stop the study treatment(s).

6. Are there benefits to being in the study?

You may or may not benefit from joining this research study. If we are able to successfully treat your tumor without the use of radiation, you will not have any of the short term or long term side effects of radiation treatment.

We hope the information learned from this study will benefit other patients with medulloblastoma in the future.

7. What are your options if you do not want to be in the study?

If you do not want to participate in this study, your alternative is to receive the standard therapy for Wnt-positive medulloblastoma or to participate in a different research study. Your doctor(s) will discuss these options with you.

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected.

8. Will it cost you anything to be in this study?

No.

9. Will you be paid if you join this study?

No.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.
- If you leave the study early, Johns Hopkins may use or give out your health information that it already has if the information is needed for this study or any follow-up activities.

11. Why might we take you out of the study early?

You may be taken out of the study if:

- Your cancer gets worse or the side effects from the study drug are too dangerous.
- Staying in the study would be harmful.
- It is not in your best interest to do so.
- You need treatment not allowed in this study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.

There may be other reasons that we don't know at this time to take you out of the study.

12. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including

your name, address, date of birth, and information from your medical records ([which may include information about HIV, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study. If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

We cannot do this study without your authorization to use and give out your information. You do not have to give us this authorization. If you do not, then you may not join this study.

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

13. Will the study require any of your other health care providers to share your health information with the researchers of this study?

As a part of this study, the researchers may ask to see your health care records from your other health care providers.

- You will be asked to give us a list of other health care providers that you use.

14. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

- <u>If you have health insurance:</u> The costs for any treatment or hospital care you receive as the result of a study-related injury will be billed to your health insurer. Any costs that are not paid for by your health insurer will be billed to you.

- If you do not have health insurance: You will be billed for the costs of any treatment or hospital care you receive as the result of a study-related injury.

By signing this form you will not give up any rights you have to seek compensation for injury.

15. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?
The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?
Call the principal investigator, Dr. Kenneth Cohen at 410-614-5055. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

If you are taking part at All Children's Hospital, call Dr. *Stacie Stapleton* at *727-767-4176.*

c. What should you do if you are injured or ill as a result of being in this study?

If you think you are injured or ill because of this study, call Dr. Kenneth Cohen at 410-614-5055 during regular office hours.

If you have an urgent medical problem related to your taking part in this study, call 410-955-6070 and ask for the Pediatric Oncologist on-call. This number is available 24 hours a day including weekends and holiday.

If you are taking part at All Children's Hospital and you have a medical problem related to your taking part in this study, call Dr. Stacie Stapleton at 727-767-4176. If this doctor is not available, the operator will page the "on call physician."

d. What happens to Data and Biospecimens that are collected in the study?

Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

16. Assent Statement

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

17. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form; you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Parent	(Print Name)	Date/Time
Signature of Person Obtaining Consent	(Print Name)	Date/Time
Signature of Legally Authorized Representative (LAR) **For CHILD PARTICIPANT**	(Print Name)	Date/Time
Description of LAR's authority under state or applicable local law to act as surrogate health care decision-maker for child research participant (for example, Legal Guardian, court-ordered representative)		Date/Time
Signature of Parent #2 (required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)	(Print Name)	Date/Time
Signature of Child Participant (optional unless IRB required)	(Print Name)	Date/Time
Signature of Witness to Consent Procedures (optional unless IRB or Sponsor required)	(Print Name)	Date/Time

I have received the separate Insurance and Research Participant Financial Responsibility Information Sheet.

Signature of Participant, LAR or Parent/Guardian	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider (Print Name) Date/Time

Signature of Parent (Print Name) Date/Time

Signature of Legally Authorized Representative (LAR) (Print Name) Date/Time
For CHILD PARTICIPANT

Description of LAR's authority under state or applicable local law to act as surrogate health care decision-maker for child research participant (for example, Legal Guardian, court-ordered representative) Date/Time

Signature of Parent #2 (Print Name) Date/Time
(required if DHHS 45 CFR 46.406 or 46.407/FDA 21 CFR 50.53 or 50.54 study)

Signature of Child Participant (optional unless IRB required) (Print Name) Date/Time

Signature of Witness to Consent Procedures (Print Name) Date/Time
(optional unless IRB or Sponsor required)

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

Addendum to Consent Form Describing the Standard of Care Chemotherapy

As explained in the consent form above, all of the chemotherapy being given on this protocol will be recommended whether you choose to participate in this study or not.

For this research, standard chemotherapy should begin within 30 days from the time of surgery.

There will be 9 cycles of chemotherapy. There are two different kinds of cycles given. They are referred to as A and B.

Cycle A lasts for 6 weeks and Cycle B lasts for 4 weeks. B cycles are given after the completion of two A cycles.

Below are the details of the drugs and schedules for A and B cycles.

Cycle A (This cycle lasts 42 days)

- Lomustine (CCNU) is given by mouth on Day 1.
- Vincristine is given directly into a vein (IV) over one minute or using a minibag over several minutes by some institutions on Days 1, 8, and 15.
- Cisplatin is given directly into a vein over 8 hours on Day 1

Cycle B (This cycle lasts 28 days)

- Cyclophosphamide is given into a vein over 1 hour on Days 1 and 2.
- MESNA, a drug to protect the bladder from the effects of cyclophosphamide, will be given 15 minutes before each dose of cyclophosphamide and repeated at 3 and 6 hours.
- Vincristine is given directly into a vein directly into the vein (IV) over one minute or using a minibag over several minutes by some institutions on Days 1 and 8.

You may also get a supportive care drug called a myeloid growth factor (filgrastim [G-CSF] or pegfilgrastim). This drug will help your blood counts recover after the chemotherapy is given.

Procedures that are part of regular cancer care and will be done even if you do not join the study:

Before treatment on this study begins and while receiving treatment, you will be given a series of standard medical tests. These include:

- Physical exams
- Blood tests
- Tests of kidney function
- Tests of liver function
- Tests of hormone function
- Hearing tests
- Magnetic Resonance Imaging (MRI) of brain and spine.
- Evaluation of cerebral spinal fluid (CSF) taken by lumbar puncture*
- Neuropsychological testing

What are the risks or discomforts of the standard chemotherapy?

While on the study, you are also at risk for the side effects described below. You should discuss these with the study doctor and/or your regular doctor. There also may be other side effects that we cannot predict. Other drugs will be given to make side effects less serious and uncomfortable. Many side effects go away shortly after the therapy is completed, but in some cases side effects can be serious or long-lasting or permanent. In rare cases, the side effects can lead to death. Other unknown side effects may occur. You will be watched closely and the treatment will be discontinued if serious side effects develop.

Risks and side effects related to the drugs given on this study include the following:

Risks and side effects related to Lomustine include those which are:

Likely	Less Likely	Rare but serious

• Nausea and/or vomiting
• Fewer white blood cells, red blood cells and platelets in the blood
  ○ a low number of white blood cells can make it easier to get infections
  ○ a low number of red blood cells can make you feel tired and weak
  ○ a low number of platelets causes you to bruise and bleed more easily
• Loss of Appetite
• Weight loss
	• Increase in the blood of certain enzymes or bilirubin (a substance that comes from the liver breaking down waste products) which could indicate liver irritation or damage
	• Inflammation and/or sores in the mouth that may make swallowing difficult and are painful (painful mouth sores)
	• (Confusion) difficulty in thinking clearly or a sense of not knowing where you are
	• Tiredness
	• Unsteadiness when walking
	• Slurred speech
		• Damage and scarring of the lungs that can lead to fluid in the lungs and affect your ability to breath and the levels of oxygen in your blood. This usually occurs only with very large doses over a long period of time.
		• Damage to the lungs which may can become worse over time and lead to death
		• Severe kidney damage (which may be permanent)
		• A decrease in the size of the kidneys
		• Damage to the nerves of the eye which may decrease vision (the ability to see clearly) and may cause blindness
		• A new cancer or leukemia resulting from this treatment

Risks and side effects related to Cisplatin include those which are:

Likely	Less Likely	Rare but serious

• Nausea and vomiting
• fewer red blood cells and white blood cells and platelets in the blood
  ○ a low number of red blood cells can make you feel tired and weak
  ○ a low number of white blood cells can make it easier to get infections
  ○ a low number of platelets causes you to bruise and bleed more easily
• Abnormal levels of magnesium in the body which may require that you take extra magnesium by mouth or in the vein
• Loss of appetite
• Damage to the ear causing difficulty in hearing high pitched sounds
• Temporary and mild increases in levels of certain chemicals in the blood because the kidney is not working as well as normal
	• Abnormal levels of certain salts in the body like sodium, calcium, potassium and phosphate
	• Metallic taste
	• Rash
	• Numbness and tingling in the fingers and toes
	• Temporary changes in vision
	• Damage to the ear causing hearing loss, balance problems and ringing in the ears
	• Elevation in the blood of certain enzymes found in the liver which may indicate liver irritation or damage
	• Inflammation and discomfort in the vein through which the medicine was given
	• Damage to the skin if the medication leaks from the vein
		• Allergic reactions which may be severe and life-threatening, causing difficulty in breathing, rapid heart rate, facial swelling and or a drop in blood pressure
		• Damage to the kidney which may be permanent
		• Deafness
		• Seizures
		• Damage to the vision which could lead to blurred vision, blue-green color blindness and to loss of vision which usually goes away after stopping the drug
		• Decrease in muscle and nerve reflexes that may affect normal functions such as walking
		• Leukemia later in life

Risks and side effects related to Cyclophosphamide include those which are:

Likely	Less Likely	Rare but serious

• Loss of appetite
• Nausea
• Vomiting
• Fewer white blood cells in the blood.
  ○ A low number of white blood cells may make it easier to get infections.
• Hair loss
• Decreased ability of the body to fight infection
• Absence or decrease in the number of sperm which may be temporary or permanent which may decrease the ability to have children
	• Abnormal hormone function which may lower the level of salt in the blood
	• Abdominal pain
	• Diarrhea
	• Fewer red blood cells and platelets in the blood
	  ○ A low number of red blood cells may make you feel tired and weak.
	  ○ A low number of platelets may cause you to bruise and bleed more easily.
	• Bleeding and inflammation of the urinary bladder
	• Absence or decreased monthly periods which may be temporary or permanent and which may decrease the ability to have children
	• Temporary blurred vision
	• Nasal stuffiness with IV infusions
	• Skin rash
	• Darkening of areas of the skin and finger nails
	• Slow healing of wounds
	• Infections
		• Heart muscle damage which may occur with very high doses and which may be fatal
		• Abnormal heart rhythms
		• Damage and scarring of lung tissue which may make you short of breath
		• A new cancer or leukemia resulting from this treatment.
		• Damage or scarring of urinary bladder tissue
		• Severe allergic reaction which can be life threatening with shortness of breath, low blood pressure, rapid heart rate chills and fever
		• Infertility which is the inability to have children

Risks and side effects related to Vincristine include those which are:

Likely	Less Likely	Rare but serious
• Hair loss • Reversible nerve problem that may affect the way you walk or the feelings in your fingers or toes • Constipation	• Jaw pain • Headache • Muscle Weakness • Pain and bloating in your abdomen • Numbness and tingling • Wrist or foot drop • Drooping eyelids • Double vision, difficulty seeing at night • Hoarseness of your voice • Difficulty sweating • Abnormal walk with foot slapping • Difficulty with urination or increased desire to urinate • Dizziness and low blood pressure when you stand • Abnormal hormone function which may lower the level of salt in the blood • A mild drop in white blood	• Complete stoppage of your intestinal activity which can result in intestinal blockage • If the drug leaks out of the vein when being administered it will cause damage to nearby tissue • Seizures • Vocal cord paralysis • Difficulty breathing • Inability to walk • Decreased ability to hear clearly • Damage to the nerve to the eye (optic nerve) leading to decreased vision and possible blindness • In combination with other chemotherapy drugs: damage to the liver which can lead to inflammation and/or scarring which could lead to a yellow appearing skin, and fluid collection in the abdomen (belly) which makes it look larger

	cells, red blood cells and platelets in the blood ○ a low number of red blood cells can make you feel tired and weak ○ a low number of white blood cells can make it easier to get infections ○ a low number of platelets causes you to bruise and bleed more easily	

All subjects may get a supportive care drug called a myeloid growth factor (filgrastim or pegfilgrastim if needed to help recover blood counts after chemotherapy. Risks and side effects related to myeloid growth factors (filgrastim (G-CSF) or pegfilgrastim) include those which are:

Likely	Less Likely	Rare but serious
• Aching or pain in the bones	• Pain, redness, itching, and hardening of the skin and bruising at the site of the injection • Headache • Higher than normal levels of liver enzymes which may indicate liver irritation or damage • Increase of uric acid in the blood • A low number of platelets in the blood which may cause you to bruise and bleed more easily • Low fever • Enlargement of the spleen (an organ in the abdomen/belly which stores blood cells) which may cause pain in the abdomen or left shoulder • Higher than normal white blood count • Skin condition marked by fever and painful skin lesions that appear mainly on the face, neck, back and arms • Rash or worsening of rash[1] • Inflammation of blood vessels in the skin leading to a raised purple rash and bruising has been seen mainly in patient who are treated for a long time[1] • Overall reddening with feelings of warmth[2]	• Allergic reactions which can be life threatening with shortness of breath, low blood pressure, rapid heart rate, hives and facial swelling. • Serious allergic reaction which can be life threatening with rapid build-up of fluid under the skin, in the lining of the intestine, and possibly in the throat or swelling of the tongue which could make it difficult to breath[2] • If you are known to have sickle cell disease, filgrastim or pegfilgrastim may cause a sickle cell crises. • Severe damage to the spleen (an organ in the abdomen/belly which stores blood cells) which could lead to pain and loss of blood into the abdomen (belly) and maybe life threatening • Difficulty breathing and lung damage that may be due to the white blood cells that are stimulated by filgrastim or pegfilgrastim traveling to the lungs when they are inflamed or infected. • A blood disorder or leukemia that has only been seen in patients with certain immune disorders who are treated for a very long time. [1]

[1] Reported with filgrastim
[2] Reported with pegfilgrastim

Risks and side effects related to MESNA include those which are:

Likely	Less Likely	Rare but serious
• Bad taste when taken by mouth	• Nausea. • Vomiting • Stomach pain • Headache • Pain in arms, legs and joints. • Tired feeling • Rash • Temporary low blood pressure • Diarrhea • Fever • Facial flushing with red cheeks • Nervousness • Dizziness • Confusion • Swelling around the eyes • Coughing • Rapid heart rate	• Severe allergic reaction which can be life threatening with shortness of breath, low blood pressure, rapid heart rate, chills and fever

J1403

JOHNS HOPKINS MEDICINE

Insurance and Research Participant Financial Responsibility Information Sheet

Clinical Research Study Title:

Pilot Study Assessing the Feasibility of a Surgery and Chemotherapy-Only Approach in the Upfront Therapy of Children with Wnt Positive Standard Risk Medulloblastoma

Principal Investigator: Kenneth Cohen MD MBA

eIRB # : NA_00091840

Date: 04/23/2014

PRA Review and Date: 09/26/2014 – CIR00004694 v2

The following procedures, tests, drugs or devices are part of this research and will be supplied free of charge by the study:

- Pathology Central Review
- Radiology Central Review
- Central Neuropathologic Analysis (Wnt Tumor Testing)
- Sequencing of Tumor Samples for Mutations of β-Catenin, optional
- Storage of Tumor Samples & Blood for Future Research Studies, optional

You and/or your health insurer will be responsible for all other procedures, tests, drugs or devices that are part of this study such as the following:

- MRI Brain (with contrast)
- MRI Spine
- CSF Evaluation
- Audiogram
- GFR or CrCl or Serum Creatinine based on age/gender
- CBC, Diff and Platelet
- Liver Function, BUN, Creatinine, Electrolytes (Ca, Mg)
- History & Physical Exam (with neurological exam)
- Endocrinology Review
- Pregnancy Test
- Central Venous Catheter
- Administration of Study Drugs
- Cisplatin IV
- Lomustine PO
- Vincristine IV
- Cyclophosphamide IV
- Mesna IV
- Filgrastim (G-CSF) or Pegfilgrastim
- Hydration
- Mannitol IV

If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

If you cannot pay the costs that are your responsibility, you may request financial assistance services. If you have received a bill, please contact Patient Financial Services (PFS) Customer Service.

CUSTOMER SERVICE & TOLL FREE PHONE NUMBERS

Toll Free# JHH Inpt./Outpt. 800.757.1700 JHH Inpt./Outpt. 443.997.0100
Toll Free# BMC Inpt./Outpt. 877.361.8702 BMC Inpt./Outpt. 443.997.0200
Toll Free# HCGH Inpt./Outpt. 866.323.4615 HCGH Inpt./Outpt. 443.997.0300